DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-22-08 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 39-55 are presently pending.

Response to Arguments

Claim Rejections - 35 USC § 112

4. The rejection of claims 39-55 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as set forth in the prior Office Action is moot in response to Applicant's amendment. However, a ground of rejection under 35 USC 112, 1st paragraph is set forth below.

5. Claims 39-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New matter).

Claim Rejections - 35 USC § 102

6. The rejection of claims 39-40, and 42-55 remain rejected under 35 U.S.C. 102(a) as being anticipated by Norris et al. (WO98/24,925), is withdrawn in response to Applicant's submission of a petition under 1.47(b) and a Declaration under 37 CFR 1.131 signed by all of the inventors of the claimed subject matter.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
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> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 39-40 and 42-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Norris et al. (US 20030125280; priority date of December 3, 1996).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Norris et al. teach nucleic acid molecules comprising tissue-specific and pathogen-specific promoters positioned upstream from a sequence from a sequence encoding ribozymes comprising a 5' autocatalytically cleaving ribozyme sequence, a catalytic ribozyme comprising a target RNA-specific binding site and a 3' autocatalytically cleaving ribozyme sequence. The Norris et al. reference further teaches wherein said catalytic ribozymes target rpoA, secA, ftsZ and dnaG RNA transcripts. This reference further teaches vectors comprising said nucleic acid molecules and those comprising multiple ribozyme structures, virions comprising said nucleic acid molecules, liposomes comprising said nucleic acid sequence, and methods for both treating and delivering said nucleic acid into cells. A specific example of a ribozyme construct disclosed by Applicants includes a construct against the *secA* gene inserted into the pClip vector (P. 44).

Additionally, Norris et al. teach lengthening the arms of the cis-acting ribozymes by 20 bases, this modification is disclosed as functioning to enhance the catalytic activity of the cis-acting elements (see page 21, last paragraph). See also Figures 5 and 6 wherein the arms of the cis-acting ribozymes are 25 nucleotides or more.

Norris et al. teach each and every aspect of the instant invention thereby anticipating applicant's claimed invention.

It is noted that Applicants have previously filed a Rule 1.131 declaration signed by all the inventors of the claimed subject matter asserting that Applicants were in possession of the claimed genus prior to June 11, 1998, however it is noted that the priority date of the published US patent application is December 3, 1996. Moreover, in

the Rule 1.132 Declaration filed 3/22/2004, Applicants asserted that Steven London and Harold May did not make any inventive contributions to claims 1, 4, 5, 7, 10, 12, 17, 19-24 26, 35, 36, and 38. It is noted that all of these claims are now cancelled, And claims 39-55 are presently pending.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 39, and 42-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norris et al. (WO 97/17433) in view of Stinchcomb et al. (US 5,599,706).

Norris et al. teach recombinant nucleic acids comprising a tissue-specific promoter upstream from a sequence encoding a 5'-autocatalytically cleaving ribozyme, a trans-acting ribozyme that binds and cleaves a selected RNA molecule. Norris et al. provides an example wherein the ribosomal RNA polymerase I(A) tissue-specific promoter binding sites is used in their ribozyme producing constructs (page 9). One particular example of the ribozyme constructs includes the pClip ribozyme cassette, which comprises a tissue specific promoter-binding site upstream from a sequence encoding a 5' autocatalytically cleaving ribozyme sequence, a catalytic ribozyme comprising a target RNA-specific binding site and a 3' autocatalytically cleaving ribozyme sequence (Figure 3).

In another embodiment of this reference, Norris et al. teaches the following regarding tissue-specific promoters, see page 8: "[A]s expected, other tissue-specific promoters can be used in the present nucleic acid constructs. Examples of these promoters include the binding sites for prostate-specific antigen (prostate), albumin (liver), fatty acid binding protein (ilium), whey acidic protein (breast), smooth muscle actin (smooth muscle), etc. It will also be clear that target-specific promoters not yet identified can be used to target expression of the present ribozymes to the selected tissue(s)."

Norris et al. also provide methods describing the delivery of the ribozyme constructs into cells by administering liposomes comprising said ribozyme constructs to said cells, see page 13, paragraphs 2-3. The ribozyme constructs of Norris et al. can also be expressed in a transformed cell line, see page 15, paragraph 3. Norris et al. also teach that the ribozyme nucleic acid constructs of their invention can be driven by virus specific promoters to specifically target their expression in, for example, HBV and HPV, see page 16, last paragraph.

However, Norris et al. does not teach wherein the number of nucleotides in one of said first arm and second arms of the autocatalytically cleaving ribozyme is about 20 nucleotides.

Stinchcomb et al. teach that the activity of a ribozyme can be optimized by varying the length of the binding arms which flank the catalytic core of the ribozyme (col. 7, lines 14-17).

Therefore, it would have been obvious to the ordinary skill in the art to combine the teachings of Norris et al. with the teachings of Stinchcomb et al. in the design of the instant invention. One of ordinary skill in the art would have been motivated to modify the ribozyme constructs of Norris et al. by varying the length of the first and second arms of the autocatalytically active ribozyme in order to optimize the activity of the ribozyme based upon the teachings of Stinchcomb et al. One of ordinary skill in the art would have had a reasonable expectation of success in modifying the binding arms of the ribozymes of Norris et al. since the prior art, e.g. Stinchcomb et al. and Norris et al. provide sufficient guidance in varying the nucleotide sequence of a given ribozyme.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

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